IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SAN ROCCO THERAPEUTICS, LLC, Plaintiff, v. BLUEBIRD BIO, INC. and THIRD ROCK VENTURES, LLC, Defendants.	)	C.A. No. 21-1478-RGA **JURY TRIAL DEMANDED** **PUBLIC VERSION**

SECOND AMENDED AND SUPPLEMENTAL COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff San Rocco Therapeutics, LLC ("SRT"), formerly known as Errant Gene Therapeutics, LLC, for its Complaint against Defendants Bluebird Bio, Inc. ("Bluebird") and Third Rock Ventures, LLC ("Third Rock") (collectively, "Defendants") hereby alleges, on knowledge as to its own actions, and upon information and belief as to all other matters, as follows:

NATURE OF THE CASE

1. This is an action for infringement of U.S. Patent Nos. 7,541,179 ("the '179 Patent") and 8,058,061 ("the '061 Patent") (collectively, the "Patents-in-Suit") pursuant to the Patent Laws of the United States, 35 U.S.C. § 100, *et seq*., including §§ 271(a), 271(b), and/or 271(c).

2. SRT has an exclusive commercial license to the '179 and '061 Patents, titled "Vector Encoding Human Globin Gene And Use Thereof In Treatment of Hemoglobinopathies," which claim recombinant vectors that are used in the treatment of hemoglobinopathies, such as Sickle Cell Disease and Beta Thalassemia.

3. SRT is a biopharmaceutical company, established in 1993 by its founder and CEO, Mr. Patrick Girondi, after his son was diagnosed with Beta Thalassemia, a rare inherited blood disorder. Since that time, and for the greater part of nearly three decades, SRT has dedicated itself

to developing treatments for life-threatening diseases, with a special focus on rare diseases (commonly referred to as orphan diseases), through the use of gene therapy — a scientific technique that treats genetic disorders by modifying, replacing, and/or inactivating mutated genes responsible for causing the disease.

4. As a result of its tireless efforts, SRT has successfully developed recombinant vectors that can be used in gene therapy treatment of rare genetic diseases, such as Sickle Cell Disease and Beta Thalassemia (also referred to as β-thalassemia). Indeed, SRT became the first company to obtain Orphan Drug Designation for Beta Thalassemia in the United States and Europe, and the first to produce a commercial batch (sufficient for 8-10 patients) of gene therapy for Beta Thalassemia.

5. SRT brings this action to protect its rights and investment in its innovations embodied in the '179 and '061 Patents infringed by Bluebird's betibeglogene autotemcel (beti-cel) gene therapy (formerly, marketed as ZYNTEGLO® and LENTIGLOBIN®), which is manufactured using (and containing) the BB305 lentiviral vector (hereinafter "the BB305 Vector" or "Infringing Drug Product").

6. SRT brings this action against Third Rock for inducing infringement of the '179 and '061 Patents by, among other things, actively and knowingly aiding and abetting Bluebird's infringement of the '179 and '061 Patents. With knowledge of SRT's exclusive (worldwide) license to the '179 and '061 Patents, Third Rock actively induced, and possessed the specific intent to cause, urge, encourage, and aid in Bluebird's direct infringement of the '179 and '061 Patents.

THE PARTIES

7. SRT is a Delaware limited liability company with its principal place of business at 308 East Emily Street, Tampa, Florida 33603.

8. Bluebird is a Delaware corporation with business offices located at 60 Binney Street, Cambridge, Massachusetts 02142, and at 188 East Blaine Street, Suite 300, Seattle, Washington 98102.

9. Third Rock is a Delaware limited liability company with business offices located at 29 Newbury Street, 3rd Floor, Boston, Massachusetts 02116, and at 499 Illinois Street, Suite 110, San Francisco, California 94158.

JURISDICTION AND VENUE

10. This action arises under the patent laws of the United States, 35 U.S.C. § 100, *et seq*., including §§ 271(a), 271(b), and/or 271(c).

11. This Court has subject matter jurisdiction over the matters asserted herein pursuant to 28 U.S.C. §§ 1331 and 1338(a).

12. This Court has personal jurisdiction over Bluebird and Third Rock at least because Bluebird and Third Rock are each incorporated in the State of Delaware.

13. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(a), 1391(c), and 1400(b) because Bluebird and Third Rock are each incorporated in this District and therefore "reside" in this District.

THE PATENTS-IN-SUIT

14. On June 2, 2009, the United States Patent and Trademark Office ("USPTO") duly and legally issued the '179 Patent, entitled "Vector Encoding Human Globin Gene and Use

Thereof in Treatment of Hemoglobinopathies," to inventors ("Inventors" and each an "Inventor") Michel Sadelain, Stefano Rivella, Chad May, and Joseph Bertino, and the '179 Patent was assigned to Memorial Sloan-Kettering Cancer Center ("MSKCC"). A true and correct copy of the '179 Patent is attached as Exhibit A.

15. The '179 Patent issued from U.S. Patent Application No. 10/188,221, which claims priority to Provisional Application Nos. 60/301,861 filed on June 29, 2001 and 60/302,852 filed on July 2, 2001.

16. On November 15, 2011, the USPTO issued the '061 Patent, entitled "Vector Encoding Human Globin Gene and Use Thereof in Treatment of Hemoglobinopathies," to Inventors Michel Sadelain, Stefano Rivella, Chad May, and Joseph Bertino, and the '061 Patent was assigned to MSKCC. A true and correct copy of the '061 Patent is attached as Exhibit B.

17. The '061 Patent issued from U.S. Patent Application No. 12/433,412, which is a division of Application No. 10/188,221 filed on July 1, 2002, now the '179 Patent. The '061 Patent claims priority to Provisional Application Nos. 60/301,861 filed on June 29, 2001 and 60/302,852 filed on July 2, 2001.

SRT has an Exclusive Commercial License to the '179 and '061 Patents

18. Pursuant to a settlement agreement executed on November 2, 2020 (the "Settlement Agreement"), MSKCC granted SRT an [redacted] to the intellectual property listed in a [redacted] D.I. 16, [Dfs' Br.], Ex. C at 2(a) of the Settlement Agreement.

19. Under the Settlement Agreement, SRT has the right to exclude others from making, having made, using, importing, selling, or offering for sale in the United States any lentiviral

vector, gene therapy treatment, or drug product that is covered by a valid claim of the Patents-in-Suit, which are the intellectual property licensed in the [redacted].

20. Under the Settlement Agreement, SRT has the right to exclude others from commercializing or engaging in commercialization activities using a lentiviral vector that is within the scope of a valid claim of the Patents-in-Suit.

21. The intellectual property licensed in the 2005 Agreement is set forth under Exhibit A thereto, and includes: U.S. Patent Application No. 10/188,221, filed on July 1, 2002, "Vector Encoding Human Globin Gene and Use thereof in Treatment of Hemoglobinopathies;" U.S. Provisional Applications Nos. 60/301,861, filed on June 29, 2001 and 60,302,852 filed on July 2, 2001; and International Application No. PCT/US2002/020988.

22. The 2005 Agreement further provides that the patent rights shall mean all of the following intellectual property: (a) the United States and foreign patents and patent applications listed in Exhibit A; (b) the United States and foreign patents issued from the applications listed in Exhibit A and from divisionals and continuations of these applications; (c) claims of U.S. and foreign continuation-in-part applications, and of the resulting patents, which are directed to the subject matter specifically described in the U.S. and foreign patent applications listed in Exhibit A; and (d) any reissues or re-examinations of patents described in (a), (b), or (c), above.

23. The '179 Patent issued from U.S. Patent Application No. 10/188,221, which is listed in Exhibit A to the 2005 Agreement. The '061 Patent is a Division of U.S. Application No. 10/188,221 filed on July 1, 2002, now the '179 Patent. The '179 and '061 Patents claim priority to U.S. Provisional Application Nos. 60/301,861 and 60/302,852, which are listed in Exhibit A to the 2005 Agreement.

24. The Settlement Agreement unambiguously states: "MSK[CC] shall [g]ive [SRT] [redacted] to the intellectual property licensed in the [redacted] which includes the '179 and '061 Patents. D.I. 16, Ex. C, ¶ 2(a).

25. MSKCC agrees that SRT has [redacted] to the intellectual property listed in the [redacted] (*i.e.*, the '179 and '061 Patents) pursuant to the Settlement Agreement. *See Errant Gene Therapeutics, LLC v. Memorial Sloan-Kettering Cancer Center and Sloan Kettering Institute of Cancer Research*, Case No. 21-cv-08206-VSB (S.D.N.Y.), D.I. 27 ["MSKCC Br."] at 3 (stating "The 2020 Settlement Agreement granted SRT a *new* [redacted] to the intellectual property licensed in the [redacted] (emphasis in original)).

26. MSKCC does not dispute that it granted SRT an exclusive commercial license to any lentiviral vector that is covered by any claim of the Patents-in-Suit. *See id*.

27. MSKCC does not dispute the scope of SRT's license, as explicitly and unambiguously, set forth in the Settlement Agreement, which states that "[SRT] . . . [has] [redacted] to the intellectual property licensed in the [redacted] *See id*. at 3. MSKCC agrees that the '179 and '061 Patents are included as the intellectual property licensed in the [redacted]. *Id*. at 3.

28. MSKCC does not dispute the construction of the Settlement Agreement that is set forth in the first 2(a) section, which clearly and unambiguously, states that "MSK shall: Give [SRT] an [redacted] to the intellectual property licensed in the [redacted]." *See id*., at 3.

29. MSKCC admits that it gave SRT an [redacted] to the intellectual property licensed in the [redacted] *See* MSKCC Br. at 3 (admitting that under the Settlement

Agreement, MSKCC granted to SRT "an [redacted] to the intellectual property licensed in the [redacted]").

30. Accordingly, MSKCC and SRT do not dispute the construction of the first 2(a) section of the Settlement Agreement that grants SRT an [redacted] to the '179 and '061 Patents.

31. The doctrine of equitable estoppel, as a matter of law, prevents MSKCC from claiming that SRT does not have an [redacted] to the intellectual property licensed in the [redacted] (*i.e.*, the '179 and '061 Patents).

32. There is no dispute between MSKCC and SRT about the scope of SRT's license as being an "[redacted]" to any lentiviral vector, transduced cells containing lentiviral vectors, and methods of making transduced cells that are covered by the claims of the '179 Patent and/or '061 Patent. However, MSKCC and SRT may disagree about the interpretation of claims of the '179 and '061 Patents as properly construed. *See, e.g., Errant Gene Therapeutics, LLC v. Memorial Sloan-Kettering Cancer Center and Sloan Kettering Institute of Cancer Researc*h, Case No. 21-cv-08206-VSB (S.D.N.Y.), D.I. 31 ["SRT's Amended Complaint"] at ¶¶ 7-10, 80-85, 113-116, 125, and 137.

33. On November 2, 2020, MSKCC transferred to SRT an undivided interest (*i.e.*, an [redacted]) in the '179 and '061 Patents.

34. Under the Settlement Agreement, MSKCC did not retain any rights to make, sell, license, use or market products within the scope of the claims of the '179 and '061 Patents.

35. Under the Settlement Agreement, MSKCC did not retain any rights to enforce or commence an infringement action on the Patents-in-Suit.

36. Under the Settlement Agreement, MSKCC is only permitted to conduct internal research using one specific lentiviral vector, and that vector is a non-clinical grade, [redacted] vector (the "[redacted]"). *See* D.I. 16, Ex. C at 2.

37. Under the Settlement Agreement, SRT and MSKCC terminated the 2011 Agreement, thereby extinguishing any prior rights and restrictions MKSCC had to enforce or commence a civil action for patent infringement.

38. Under the Settlement Agreement, SRT and MSKCC terminated the 2011 Agreement, thereby extinguishing any rights MSKCC had to make, sell, license, use or market products within the scope of the claims of the '179 and '061 Patents.

39. As of November 3, 2020, SRT has an exclusive (worldwide) commercial license to any process, service, or any product, or part thereof made, used or sold that is covered by any claim of the '179 Patent and/or the '061 Patent for any field of use.

40. As of November 3, 2020, SRT has an exclusive (worldwide) commercial license to any process, service, or any product, or part thereof made, used, or sold that is manufactured by using a process covered by any claim of the '179 and/or the '061 Patent for any field of use.

41. As of November 3, 2020, as an exclusive licensee, SRT is able to commence an action for infringement when the patent owner refuses to vindicate SRT's rights.

42. As of November 3, 2020, SRT has the primary responsibility for enforcing the patent rights to the '179 and '061 Patents because SRT is the exclusive (worldwide) commercial licensee having all substantial rights in the Patents-in-Suit.

43. As the exclusive (worldwide) commercial licensee, SRT has standing to bring this action in its own name, without joining MSKCC, because "all substantial rights" in the Patents-

in-Suit were transferred to SRT pursuant to its [redacted] to the Patents-in-Suit granted under the Settlement Agreement.

44. As the exclusive (worldwide) commercial licensee, SRT has the constitutional right under the Patents-in-Suit to exclude Bluebird from engaging in its infringing activity and conduct which has injured SRT.

FACTS AND CLAIMS THAT LEAD TO THE SETTLEMENT AGREEMENT WITH MSKCC

45. SRT has diligently worked and expended substantial sums of money for the development of lentiviral vectors in collaboration with Inventors Drs. Michel Sadelain and Stefano Rivella.

46. In 2000, SRT began financially supporting the research of Inventors Drs. Sadelain and Rivella, both of whom were researchers at MSKCC, and had published a paper on their experiments with gene therapy for treating Beta Thalassemia in mice.

47. SRT's tireless efforts, and work with Inventors Drs. Sadelain, Rivello and others, resulted in the development of the TNS9 Vector for the treatment of Beta Thalassemia.

48. SRT committed every available resource at its disposal to produce the TNS9 Vector — what became trademarked by SRT as Thalagen — in accordance with the U.S. Federal Drug Administration's ("FDA") stringent approval process for investigational new drugs ("IND").

49. In addition, SRT diligently, through various agreements with MSKCC and other top medical centers, continued testing and refining the TNS9 Vector to ensure patient safety, and to ensure conformance with the highest manufacturing and testing standards, designated by the FDA as chemical Good Manufacturing Practice ("cGMP").

50. SRT's Director of Gene Therapy, Dr. Christopher Ballas, created an innovative and proprietary process related to lentiviral vector production, which is worth in excess of hundreds of millions of dollars.

51. In 2007, MSKCC's work to make a clinical grade vector was failing and, in fact, MSKCC's lentiviral vector production was inefficient and not ready to treat patients.

52. In 2007, SRT evaluated and improved (i) the lentiviral-based transduction of CD34+ cells; and (ii) determined TNS9 lentiviral integration using Taqman multiplexed Q-PCR. In addition, SRT evaluated and improved the (i) filtration of lentiviral vectors and (ii) worked on the preparation of CD34+ methocult-based colony formation assays.

53. In 2007, SRT became the first entity to pass the FDA Recombinant DNA Committee for gene therapy in Beta Thalassemia (and future applications in Sickle Cell Disease).

54. In 2008, SRT successfully requested a pre-IND meeting with the FDA to advance to clinical (*i.e.*, human) trials, the next stage necessary to develop the TNS9 Vector.

55. On September 1, 2010, SRT completed the manufacture and production of a batch of the TNS9 Vector in an amount sufficient to treat 8-10 patients in a Phase I clinical trial. The physical production of the TNS9 Vector alone cost $1,300,000.

56. Armed with the first commercial batch of the TNS9 Vector, SRT was eager to begin the clinical trial. MSKCC requested that SRT deliver the TNS9 Vector to MSKCC for use in a mobilization study. SRT, completely trusting of their partner, complied pursuant to the 2005 Agreement.

57. In October 2010, MSKCC demanded a $4 million (for a 10 patient trial at $400,000 per patient) cash advance from SRT before it would allow any clinical trial involving the TNS9 Vector to take place at MSKCC.

58. Given that part of SRT's mission was to make gene therapy treatment not only safe, but affordable to patients, SRT refused to agree to such a demand. Moreover, Dr. John Tisdale, the then-SRT Principal Investigator on the Beta Thalassemia gene therapy project at the National Institutes of Health ("NIH") was willing to hold the clinical trial and treat patients for less than $50,000 each. Using the NIH would save over $3 million in funding that could be used for further Beta Thalassemia research. Thus, it would have been fiscally irresponsible for SRT to pay MSKCC 8 times more for a comparable service.

59. SRT also refused MSKCC's $4 million cash demand because MSKCC could not guarantee that the clinical trial would be completed, and meanwhile, the FDA wanted a patient to be treated every 3 months. Indeed, as of the filing of this action, MSKCC has treated only 4 patients with the TNS9 vector.

60. Desperate to begin clinical trials and to work towards finding a cure for his son, Mr. Girondi and SRT sent a living organism courier to pick up the TNS9 Vector from MSKCC in March 2011. MSKCC refused to return the TNS9 Vector to SRT.

61. Given that many months had passed without treating a single patient with the TNS9 Vector, SRT met with MSKCC on June 16, 2011. At the June 16, 2011 meeting, MSKCC proposed a new agreement: MSKCC would take control of the clinical trial from SRT and MSKCC would head the commercialization of the TNS9 Vector. In addition, MSKCC and its representatives repeatedly stated that MSKCC had already spent significant funds to draft the IND application, that the IND application was complete and ready to be filed immediately, and that MSKCC would treat patients with SRT's TNS9 Vector by October 2011.

62. Due to SRT's strong desire to move forward with the clinical trial and the IND application process with the FDA, MSKCC's representations induced SRT to execute an

agreement dated June 17, 2011 (the "2011 Agreement"), whereby MSKCC assumed the right to commercially develop the TNS9 Vector, and SRT maintained 50% of the upside of the gene therapy project.

63. With the 2011 Agreement, SRT believed that the potential to commercialize and realize profits from SRT's TNS9 Vector would motivate MSKCC to aggressively proceed to the market with it. But that was not the case. In fact, MSKCC did not file the IND application until September 2011, which the FDA flatly rejected as incomplete. And it was not until over 9 months later, and nearly a year after the June 16, 2011 meeting, that the FDA accepted the IND.

64. From November 2011 through June 2013, an additional two years later, MSKCC treated the first 3 out of 7-10 (intended) patients with the TNS9 Vector. By 2015, MSKCC claimed that they had no funding to proceed with the clinical trial and were no longer actively pursuing the exploitation of SRT's TNS9 Vector. Yet MSKCC still refused to return the TNS9 Vector to SRT.

65. Thus, beginning in 2015, SRT sought the return of the TNS9 Vector, including any and all information (laboratory, clinical or otherwise) related thereto. When MSKCC (again) refused to return the TNS9 Vector, SRT commenced a civil action against MSKCC in the Supreme Court of the State of New York entitled, *Errant Gene Therapeutics, LLC v. Sloan Kettering Institute for Cancer Research and Bluebird Bio, Inc*., Index. No. 150856/2017 (N.Y. Cty. Sup. Ct.) for the following causes of action: fraud, breach of contract, and civil conspiracy to defraud.

FACTS AND CLAIMS THAT LEAD TO THE SETTLEMENT AGREEMENT WITH BLUEBIRD

66. SRT commenced a civil action against Bluebird Bio in the Supreme Court of the State of New York entitled, *Errant Gene Therapeutics, LLC v. Sloan Kettering Institute for Cancer Research and Bluebird Bio, Inc*., Index. No. 150856/2017 (hereafter the "New York Litigation"),

for the following causes of action: conspiracy to defraud, unfair competition, and unjust enrichment. See D.I. 16, [Defendants Br.], at exhibit D attached thereto.

67. SRT commenced a civil action against Third Rock Ventures, LLC and Nick Leschly in the Commonwealth of Massachusetts, Superior Court Department of the Trial Court, entitled *Errant Gene Therapeutics, LLC v. Third Rock Ventures, LLC and Nick Leschly*, Civil Action No. 19-1832, (hereafter the "Massachusetts Litigation") for the following causes of action: tortious interference with contractual relations, tortious interference with business relations, misappropriation of trade secrets, civil conspiracy, unjust enrichment, and violations of Massachusetts General Laws ch. 93A. *See* D.I. 16, Ex. E.

68. SRT took great care to protect and guard the secrecy of its clinical data, know-how, and other trade secrets, including the physical TNS9 Vector.

69. SRT alleged that Bluebird fraudulently obtained physical possession of SRT's TNS9 Vector and its proprietary recipe and titration process related to the formulation of safe clinical grade lentiviral vectors.

70. SRT alleged that Sloan-Kettering Institute for Cancer Research ("SKI") and Bluebird entered into a secret partnership and conspiracy for the purpose of obtaining physical possession of SRT's TNS9 Vector and prevent completion of SRT's clinical trials.

71. SRT's conspiracy and fraud allegations were rooted in the interlocking relationship between executives of SKI and Bluebird.

72. Bluebird could not efficiently and safely produce lentiviral vectors that were safe for clinical use in patients. For example, on November 27, 2017, the New York Times published an article titled "Gene Therapy Hits a Peculiar Roadblock: A Virus Shortage," which stated the following:

> Few gene-therapy companies have the factories or expertise to make the viruses for use in clinical trials, where **standards are exacting and comprehensive . . . .**
>
> [A]s officials at Bluebird Bio can attest, whether you have any product at all. The company was formed in 2010, hoping to show that gene therapy could work in adrenoleukodystrophy, a rare and fatal neurodegenerative disease that strike boys. That was before the virus production logjam had begun, and all seemed well. Bluebird gave a virus manufacturer its recipe for making needed viruses.
>
> Then, said Nick Leschly, the company's chief executive, he got bad news. **Using Bluebird's recipe, the manufacturing company said it was going to cost Bluebird a million dollars to create enough viruses to treat one patient**.
>
> The company scurried to find ways to **improve the efficiency of its recipe**. Finally, they were ready to start anew. Manufacturing began, but months later there was nothing to show for it.
>
> "**We got no virus**," Mr. Leschly said. "It was an Apollo 13 moment," he added. "We put everyone in a room and said, 'We have to figure this out. Everything at the company is now stopped. Nothing can be done without virus.'"
>
> They finally found the source of the problem — the acidity of the solution used to grow the viruses was slightly off, killing them.

Exhibit C, Gina Kolata, *Gene Therapy Hits a Peculiar Roadblock: A Virus Shortage*, N.Y. Times, (Nov. 27, 2017) (emphasis added).

73. SRT alleged that Bluebird's gene therapy was unsafe because of improper dominance of certain cell growth during a clinical trial performed on thalassemia patients by Genetix Pharma. D.I. 16, Ex. D. ¶ 47. SRT also alleged that Defendants approached MSKCC to purchase SRT's TNS9 lentiviral vector. *Id.* at ¶¶ 47-49.

74. SRT alleged that SKI breached its contract with SRT, and MSKCC's scientists were working with Bluebird for free to develop a vector for Bluebird, but this proposed vector was not the BB305 lentiviral vector.

75. Unable to acquire the TNS9 Vector directly from SRT, Bluebird allegedly entered into and engaged in a conspiracy and partnership with SKI to fraudulently wrest control of the TNS9 Vector from SRT and to eliminate Bluebird's competition.

76. The central issue in the New York and Massachusetts Litigations (collectively, the "Prior State Court Litigations") concerned conspiracy and fraud to obtain physical possession of SRT's TNS9 Vector and proprietary know-how (*e.g.*, recipe) for refining titration of lentiviral vectors to ensure patient safety conformance.

77. On November 2, 2020, the parties entered into the Settlement Agreement, which included a mutual general release to "all claims, both at law and in equity, accrued or unaccrued, know [*sic*] or unknown, suspected or unsuspected that were brought or could have been brought by SRT in the New York Litigation and the Massachusetts Litigation." D.I. 16, Ex. C at section 5 ("Mutual Release"). The Mutual Release only applies to claims that SRT may have or ever had against MSKCC or Bluebird "from the beginning of the world to the Parties' execution of" the "Settlement Agreement." *Id*.

78. The Settlement Agreement was executed by SRT, MSKCC, and Bluebird on November 2, 2020. Third Rock was not a party to the Settlement Agreement.

79. The settlement agreement arose from SRT's assertion that Bluebird and MSKCC's executives sabotaged SRT's, life-saving vector, TNS9; stalled SRT's clinical trials; and obtained SRT's proprietary recipe for making a lentiviral vector safe for clinical use.

80. Patent infringement was not a claim that could have been brought by SRT against Bluebird in the Prior State Court Litigations.

81. SRT did not have an exclusive commercial license to the '179 and '061 Patents at the commencement of (or during) the Prior State Court Litigations.

82. The Dispute Resolution provision in the Settlement Agreement does not apply to SRT's patent infringement claims in this action because this dispute between SRT and Bluebird does not concern any actual or alleged breach of the Settlement Agreement. *See id*., at ¶ 7.

83. SRT's trade-secrets related to lentiviral titration and formulation is not disclose or covered by the Patents-in-Suit. The Patents-in-Suit are not related to any commercial manufacturing, recipe or titration process for making lentiviral vectors that are safe for clinical use.

84. The scope of the claims of the '179 and '061 Patents was not at-issue, in-dispute, or discussed in the Prior State Court Litigations that lead to the execution of the Settlement Agreement nor was it discussed during settlement negotiations.

85. The claims of the '179 and '061 Patents were not asserted, at-issue, in-dispute or discussed during the Prior State Court Litigations that lead to the execution of the Settlement Agreement nor were the patent claims discussed during settlement negotiations.

86. The identity of the actual lentiviral vector contained in transduced cells used in Bluebird's gene therapy treatments during its failed clinical trials was not at-issue, examined, or discussed during the Prior State Court Litigations that lead to the Settlement Agreement between SRT and Bluebird.

87. The identity of the actual lentiviral vector contained in transduced cells to be used in Bluebird's proposed gene therapy treatments was not known, at-issue, or discussed during settlement negotiations with Bluebird that lead to the execution of the Settlement Agreement.

88. The BB305 lentiviral vector was not at-issue or disclosed in the Prior State Court Litigations that lead to the Settlement Agreement with Bluebird.

89. The BB305 lentiviral vector was never specifically referenced and identified by any party in any pleading in the Prior State Court Litigations.

90. Whether the BB305 lentiviral vector is covered by a valid claim of the '179 and/or '061 Patents, as properly construed, was not at-issue or discussed during the Prior State Court Litigations that lead to the Settlement Agreement with Bluebird.

91. Bluebird did not have a commercial license to the intellectual property licensed in [redacted] prior to or during the Prior State Court Litigations that lead to the Settlement Agreement.

92. SRT obtained its full [redacted] to the intellectual property licensed in the [redacted] (*i.e.*, the '179 and '061 Patents) on November 3, 2020, after execution of the 2020 Settlement Agreement.

93. MSKCC did not grant Bluebird any type of license, including without limitation a commercial license, to the Patents-in-Suit.

94. Bluebird has never had or been granted a commercial license to the Patents-in-Suit.

BLUEBIRD INFRINGES THE '179 AND '061 PATENTS AND IS DOING SO WILLFULLY

95. As of November 3, 2020, Bluebird was aware that SRT had an [redacted] to the intellectual property licensed in the [redacted] that includes the '179 and '061 Patents.

96. As of November 3, 2020, after execution of the Settlement Agreement, Bluebird should not have engaged in any commercialization activities concerning the BB305 Vector until after expiration of the Patents-in-Suit, if Bluebird believed doing so would infringe a valid claim of the Patent-in-Suit.

97. With respect to the BB305 Vector, Bluebird is engaging in infringing activities that are outside the scope of 35 U.S.C. § 271(e)(1), and its activities are not solely for uses reasonably related to the development and submission of information to the U.S. Food and Drug Administration ("FDA").

98. In 2015, the FDA granted Breakthrough Therapy designation to Bluebird's Infringing Drug Product for the treatment of transfusion-dependent patients with Beta Thalassemia, which is intended to expedite the development and review of the Infringing Drug Product and includes the same benefits as Fast Track designation. *See* Exhibit D ("FDA Grants Breakthrough Therapy Designation to LentiGlobin for Treatment of Beta Thalassemia Major").

99. In September 2021, Bluebird completed the submission of its Biologics License Application ("BLA") to the FDA for its Infringing Drug Product, which is manufactured using (and containing) the BB305 Vector. However, Bluebird has engaged and continues to engage in non-regulatory conduct and post-FDA submission activities related to the commercialization of the BB305 Vector, which infringes the '179 and '061 Patents.

100. On November 22, 2021, Bluebird announced that the FDA has accepted the BLA to betibeglogene (beta-cel) for priority review and the FDA has set a Prescription Drug User Fee Act (PDUFA) goal date of May 20, 2022. Ex. E, Bluebird's Nov. 22, 2021 Press Release.

101. On January 18, 2022, Bluebird announced that the FDA has extended the review period for the BLA for its lentiviral vector gene therapies — betibeglogene (beti-cel) for Beta-thalassemia and that revised PDUFA goal dates for beti-cel is August 19, 2022. Ex. F, Bluebird's Jan. 18, 2022 Press Release. Bluebird's announcement further stated that the FDA extended the PDUFA goal dates for beti-cel to allow time to review additional clinical information previously

submitted by the company and the extension of the FDA review timeline does not relate to new safety events for beti-cel.

102. With respect to the BB305 Vector, Bluebird's employees engage with community and hospital Health Care Providers ("HCPs") focused on hemoglobinopathies and bone marrow transplants to facilitate consideration of patients for gene therapy and refer appropriate patients to a Bluebird Qualified Treatment Center ("QTC" or "QTCs").

103. With respect to the BB305 Vector, Bluebird engages in developing go-to-market, local and account-based strategies, and in a manner that conditions the market for one-time gene therapies and Bluebird's first U.S. product launch.

104. With respect to the BB305 Vector, Bluebird's employees engage in: (i) organizing, and leading market development programs to build awareness of Bluebird's gene therapy product portfolio, including the BB305 Vector, and provide disease and gene therapy education; (ii) delivering Bluebird's gene therapy products' clinical information and reimbursement information to support access to Bluebird's portfolio; and (iii) advancing and deepening relationships with professional local/regional opinion leaders, QTC staff, hospital administrators, and other relevant external stakeholders that are essential partners in creating opportunities for patients.

105. With respect to the BB305 Vector, Bluebird's employees currently engage in: (i) building and executing a comprehensive account plan for QTCs, referral networks, and community practices and managing approved resources; (ii) partnering with market access, patient services, marketing, field medical affairs, and other internal Bluebird team members to ensure HCPs and other account-based decision-makers have timely access to clinical, health, economic,

and outcome research information; and (iii) participating in patient advocacy, outreach, and identification with local advocacy organizations.

106. With respect to the BB305 Vector, Bluebird's employees have (i) attended conferences to promote the BB305 Vector and (ii) implemented the company's Sickle Cell Disease strategic sales plan for the BB305 Vector.

107. Bluebird is currently engaged in expanding its U.S. commercial manufacturing capabilities for the BB305 Vector. According to its corporate statements, Bluebird is committed to investing in the capabilities and infrastructure necessary to support commercialization both in the U.S. and Europe, which includes commercialization of the BB305 Vector. *See* Exhibit G ("bluebird bio and apceth Biopharma Establish Commercial Drug Product Manufacturing Agreement").

108. Bluebird is engaging in stock-piling, ramp-up manufacturing, commercial manufacturing, marketing, and other commercialization activities for the BB305 Vector that are not reasonably related to obtaining FDA approval.

109. Bluebird has made (and continues to make) batches of the BB305 Vector that were used (and will continue to be used) for other business purposes, and which are not manufactured for use by Bluebird for FDA purposes.

110. Bluebird made batches of the BB305 Vector for use in manufacturing capacity development and yield optimization for purposes of commercialization of the BB305 Vector drug product.

111. Bluebird's Infringing Drug Product was cleared to market in Europe, where it was previously sold under the brand names LENTIGLOBIN (for Sickle Cell Disease) and ZYNTEGLO (for Beta Thalassemia).

112. In 2017, Bluebird applied for a U.S. trademark registration of the name LENTIGLOBIN in International Class 005 for "Pharmaceutical preparations and substances for the treatment of genetic diseases," and was issued the trademark registration by the USPTO in 2019, and maintains that registration with the USPTO.

113. In 2019, Bluebird applied for a U.S. trademark registration of the name ZYNTEGLO in International Class 005 for "pharmaceutical preparations and substances for the treatment of genetic diseases" and in International Class 042 for "pharmaceutical research and development," and was issued the trademark registration by the USPTO in 2020, and maintains that registration with the USPTO.

114. In 2019, Bluebird applied for a U.S. trademark registration of the ZYNTEGLO™ logo in International Class 005 for "pharmaceutical preparations and substances for the treatment of genetic diseases," and was issued the trademark registration by the USPTO in 2020, and maintains that registration with the USPTO.

115. With respect to the BB305 Vector, Bluebird has marketed development programs to build awareness of the BB305 Vector, and provided marketing information related to the BB305 Vector's clinical information and reimbursement information to HCPs.

116. Bluebird has engaged in developing and is currently partnered with QTCs for the treatment of patients with the BB305 Vector in the commercial setting in anticipation of obtaining FDA approval of the BB305 Vector.

117. With respect to the BB305 Vector, Bluebird has established commercial drug product manufacturing agreements with contract development and manufacturing companies in the field of cell and gene therapy, such as, for example, apceth Biopharma GmbH, Brammer Bio,

Novasep, and SAFC Carlsbad, Inc. *See*, *e.g.*, Exhibit H (bluebird bio, Inc. Form 10-K, dated Feb. 21, 2019 at 17).

118. Bluebird uses a commercial manufacturing facility in Durham, North Carolina for ramping up manufacturing and stock-piling the BB305 Vector. The Durham facility produces clinical and commercial supplies of the BB305 Vector on behalf of Bluebird. *See*, *e.g.*, Exhibit I ("bluebird bio Opens State-of-the-Art Gene and Cell Therapy Manufacturing Facility in Durham, North Carolina").

119. In addition, Bluebird has multi-year agreements with manufacturing partners in the United States and Europe (*e.g.*, Brammer Bio, Novasep and SAFC Carlsbad, Inc.) for commercial production of the BB305 Vector, including the importation of the Infringing Drug Product. *See*, *e.g.*, Exhibit J (bluebird bio, Inc. Form 10-K, dated Feb. 23, 2021 at 93).

120. In June 2016, Bluebird entered into a strategic manufacturing agreement with Lonza Houston, Inc. ("Lonza") for the commercial production of Bluebird's BB305 Vector. Under this agreement, Lonza is currently conducting process validation for the commercial batches of Bluebird's BB305 Vector prior to its anticipated commercial launch. *See*, *e.g.*, Exhibit K (bluebird bio, Inc. Collaborations).

121. In May 2020, Bluebird expanded its manufacturing agreement with Minaris Regenerative Medicine GmbH ("Minaris") to provide for commercial drug product manufacturing in both the United States and Europe for the BB305 Vector. *See*, *e.g.*, Exhibit K; *see also* Exhibit J at 9.

122. In addition, Bluebird relies on specialized third-party testing organizations to confirm the quality of the BB305 Vector in the commercial context. *See*, *e.g.*, Exhibit J at 9.

123. Bluebird's arrangements with its manufacturing partners were specifically designed to support the commercialization of the BB305 Vector.

124. In its agreements, Bluebird's manufacturing partners are required to provide rolling forecasts for the BB305 Vector on a quarterly basis, a portion of which will be considered binding, firm orders, subject to a purchase commitment. *See* Exhibit J at 9.

125. Bluebird has made systematic attempts to meet U.S. regulatory requirements to obtain marketing approval for its BB305 Vector drug product.

126. Bluebird's current commercialization and other business activities, including the production of batches of the BB305 Vector, are specifically for business purposes, and as such, Bluebird infringes the Patents-in-Suit.

SRT HAS SUFFERED IRREPARABLE HARM IN EXCESS OF TWO BILLION DOLLARS AS A RESULT OF DEFENDANTS' INFRINGEMENT

127. SRT committed every available resource at its disposal to produce the TNS9 Vector — what became trademarked by SRT as THALAGEN® — in accordance with the FDA's stringent approval process for investigational new drugs ("IND").

128. In addition, SRT, through various industrial research agreements with MSKCC and other top medical centers, diligently continued testing and refining the TNS9 Vector to ensure patient safety conformance with the highest manufacturing and testing standards, designated by the FDA as chemical Good Manufacturing Practice ("cGMP").

129. In 2006, SRT was the first company to be awarded Orphan Drug Designation for its vector in the U.S.; however, Bluebird received Orphan Drug Designation in 2013, seven years later.

130. In 2007, SRT became the first entity to pass the FDA Recombinant DNA Committee for gene therapy in Beta Thalassemia (and future applications in Sickle Cell Disease); however, Bluebird passed the Recombinant DNA Committee in 2012, five years later.

131. In 2008, SRT successfully completed a pre-IND meeting with the FDA to advance to clinical (*i.e.*, human) trials, the next stage necessary to develop the TNS9 Vector; however, Bluebird had its pre-IND meeting in 2012, four years later.

132. In 2009, SRT was awarded Orphan Drug Designation in Europe four years ahead of Bluebird. Bluebird received the designation in 2013.

133. On September 1, 2010, SRT completed the manufacture and production of a batch of the TNS9 Vector in an amount sufficient to treat 8-10 patients in a Phase I clinical trial. Bluebird did not have a product until 2013.

134. Mr. Patrick Girondi, the founder and CEO of SRT, is the father of a Beta Thalassemia patient. SRT's goal is to make gene therapy accessible for all patients. SRT's gene therapy product is projected to cost much less — ***over 1 million dollars less*** — per patient than Bluebird's Infringing Drug Product, which is projected to cost over 2 million dollars per patient.

135. SRT has an exclusive worldwide right and license to the '179 and '061 Patents, including the right to sublicense and/or practice the methods embodied by the '179 and/or '061 Patents, to make, have made, use, lease and sell, import and otherwise dispose of any vector (or licensed product) covered by the '179 and/or '061 Patents.

136. Bluebird had knowledge of the '179 and '061 Patents as of their date of issuance and Bluebird knew that its BB305 Vector infringes the '179 and '061 Patents.

137. Bluebird identified and cited U.S. Publication No. 2009/0274671 for the Patents-in-Suit as prior art to Bluebird's U.S. Patent No. 9,783,822, titled "Gene Therapy," which was filed in January 2015.

138. Bluebird has had actual knowledge that SRT has an exclusive (worldwide) commercial license to the '179 and '061 Patents since as of November 3, 2020.

139. At a minimum, Bluebird was willfully blind to the fact that the BB305 Vector infringes the '179 and '061 Patents, and acted, despite a risk of infringement, that was either known or so obvious to Bluebird that Bluebird should have known, that its BB305 Vector infringes the '179 and '061 Patents.

140. Bluebird's willful infringement of the Patents-in-Suit has damaged SRT. SRT is entitled to recover damages sustained as a result of Bluebird's past and present wrongful infringing acts in an amount to be determined at trial.

141. Given the imminent and irreparable harm, SRT seeks a permanent injunction and may seek a preliminary injunction to stop Bluebird from continuing the infringement of SRT's patent rights and from making, having made, using, importing, selling, or offering for sale the BB305 Vector in the United States.

THIRD ROCK IS LIABLE AS AN INFRINGER FOR ACTIVELY INDUCING BLUEBIRD'S INFRINGEMENT OF THE PATENTS-IN-SUIT

142. Since 2009, Third Rock has had (and continues to have) the specific intent to aid and abet in Bluebird's direct infringement of the '179 and '061 Patents, and even before the formation of Bluebird, Third Rock knew that the BB305 Vector would infringe the '179 and '061 Patents.

143. In a September 2009 email, Third Rock's founder Nick Leschly wrote to Inventor Sadelain regarding a "Third Rock Visit to MSKCC / Dr. Sadelain."

144. In an October 5, 2009 email, Inventor Sadelain wrote to Nick Leschly (Third Rock) and Philip Reilly (Third Rock), in which he informed Third Rock that "it may be more appropriate for you and Phil to meet with [SRT], to whom we have licensed our globin-related technology and with whom we are planning clinical trials in the US and Europe, than with MSKCC."

145. In an October 8, 2009 email, Inventor Sadelain wrote to Nick Leschly (Third Rock), Sam Salman (President of SRT), and Philip Reilly (Third Rock) about the subject "MSKCC globin gene transfer program and [SRT]."

146. In the October 8, 2009 email to Nick Leschly (Third Rock), Philip Reilly (Third Rock), and Sam Salman (SRT), Inventor Sadelain wrote the following:

> It is my pleasure to introduce you to each other, at least by e-mail. I recently met Nick's colleague Dr. Philip Reilly, at a meeting focusing on gene therapy for hemophilia. Phil and Nick recently informed me of their growing interest in the genetic treatment of several orphan disorders, including thalassemia.
>
> They have requested to meet with me to further discuss our plans for the treatment of globin disorders. Since MSKCC has licensed our globin vector technology to [SRT], Dr. Viviane Martin, who heads MSKCC's Office of Industrial Affairs, has recommended that Third [*sic*] Third Rock Ventures directly contact Sam Salman, President of [SRT]. You are now in contact….!
>
> I remain available if you need me at any point.

(Ellipses in original).

147. In May 2010, Third Rock again approached MSKCC to purchase the globin lentiviral vector intellectual property covered by the '179 and '061 Patents, knowing that SRT had a license to the '179 and '061 Patents.

148. In a May 2, 2010 email, Mitchell Finer (Genetix Pharmaceuticals, Inc. ("Genetix")), together with Nick Leschly (Third Rock) and Philip Reilly (Third Rock) wrote to Inventor Sadelain stating:

> Michel, our interests are in building the best gene therapy company to treat severe genetic disease. . . . with Third Rock . . . joining us, we have the ability to build beyond the existing

> activities at Genetix to insure success. What Phil [Third Rock] and I would like to do is to update you on our progress and plans in thal and other activities at the company. We would like to get an update on your progress and plans as well. We would follow-up with a discussion of what potential synergies and how we could work together. Let me know what you think.
>
> Thanks, Mitch.

149. In a May 3, 2010 email, Viviane Martin of MSKCC's Office of Industrial Affairs wrote to Inventor Sadelain:

> I don't quite see how 3rd Rock/Genetix can make the best out of MSK/Genetix technology w/o [without] letting one sit on a shelf. Also they [*i.e.*, Third Rock] know that we entered into a license with [SRT], and they are coming to you, not to [SRT] when they [*i.e.*, Third Rock] perfectly knew that they [*i.e.*, Third Rock] should talk to [SRT] to get rights to the technology. I honestly do not see what they are seeking . . . besides them doing competitive intelligence.

(Ellipses in original).

150. In a May 27, 2010 email, Mitchell Finer (Genetix) wrote to Patrick Girondi (SRT) stating the following:

> I want to introduce myself as the CSO of Genetix. I don't want to get in the way with the business discussions that you are having with Nick [Third Rock] and Phil [Third Rock], but I want to reiterate our commitment to have a serious discussion with you and your colleagues. . . . I've been in the gene therapy field doing research and drug development through market launch for 25+ years . . . Michel [Sadelain] can provide a reference for the quality of my science.
>
> I also understand your sense of urgency of having these discussions – I'm also the parent of a child with a genetic disorder and while her condition is not as severe as beta thalassemia, that life experience has pushed [me] very hard . . . when working with companies, foundations and when I was actively doing drug development in the field of her disorder harder compared to people who are only doing drug development as an academic or business pursuit.
>
> So please accept our apologies in the delay in getting back to you – Nick [Third Rock] and Phil [Third Rock] will contact you soon. I have the greatest scientific respect for Michel [Sadelain's] . . . work and its potential to impact the thalassemia community.
>
> Thanks for your patience.

151. In a June 1, 2010 email, Mitchell Finer (Genetix) wrote to Patrick Girondi (SRT) about scheduling a meeting with the Third Rock Team, and in that email Mitchell Finer copied Nick Leschly (Third Rock), Neil Exter (Third Rock), and Philip Reilly (Third Rock).

152. On or about June 8, 2010, Sam Salman, President of SRT, and Patrick Girondi visited Neil Exter and Nick Leschly of Third Rock to discuss a potential collaboration for a meaningful therapy; however, it was only after SRT's insistence that the meeting with Third Rock was finally held.

153. In June 2010, Third Rock attempted to collaborate with SRT and/or acquire SRT's intellectual property rights to the globin lentiviral vectors, but the negotiations broke down.

154. In a June 2010 email, Inventor Sadelain wrote to SRT stating: "The stakes are very high now and in the next few weeks. You can count on GP [now Bluebird] to proactively sabotage all your efforts."

155. In a June 18, 2010 email, Nick Leschly (Third Rock) wrote to Mitch Finer (Genetix) regarding an "updated list," in which Nick Leschly (Third Rock) stated: "Pat Girondi [SRT] – need to shut him down…curious what he called about…my emails were clear want to get him to buy into a CDA to review Michel's data. Be nice, suck up, etc…if you think (and I think) that Michel has valuable data[.]" (Ellipses in original).

156. In a September 9, 2010 press release, Genetix stated that (i) "it has changed the company name from Genetix Pharmaceuticals, Inc. to bluebird bio, Inc., effective immediately," and (ii) "bluebird bio has also announced that Nick Leschly, formerly interim president of bluebird bio and partner of Third Rock Ventures, has been appointed the company's president and chief executive officer."

157. Genetix's September 9, 2010 press release further stated that Nick Leschly is a "partner of Third Rock Ventures since its founding in 2007, he became interim president of bluebird bio in March 2010 in conjunction with Third Rock's investment in the company's Series B round. Mr. Leschly has played an integral role in the identification, formation and business strategy of several of Third Rock's portfolio companies."

158. Genetix's September 9, 2010 press release further stated that "Robert Tepper, M.D., partner at Third Rock Ventures, will join bluebird bio's board of directors on behalf of Third Rock. . . He co-founded Third Rock Ventures in 2007."

159. It was Third Rock's intent to create Bluebird specifically for the purpose of commercializing and selling a lentiviral vector, such as the BB305 Vector, that infringes the '179 and '061 Patents, and Third Rock knew that the manufacturing, commercialization, and sale of the BB305 Vector would infringe the '179 and '061 Patents.

160. On October 9, 2010, Nick Leschly wrote to SRT's CEO, Patrick Girondi: "Pat – I remain unmoved regarding meeting in person – we would get nowhere...just look at our emails...circular." (Ellipses in original.) In response, Patrick Girondi stated: "Nick, I have patients and investors. If we sign CDA's and still can't come to terms we are no better off. As I said. I try to look at every angle, even the difficult ones. I owe it to them."

161. Third Rock caused Bluebird to infringe the '179 and '061 Patents with the intent of making Bluebird a profitable company. Bluebird was the first-ever initial public offering of a Third Rock portfolio company when it went public in June 2014, during which time Third Rock owned a substantial portion of Bluebird.

162. Third Rock continues to own a substantial portion of Bluebird, and continues to financially benefit from Bluebird's infringement of the '179 and '061 Patents. Bluebird traded a

market cap of approximately 13 billion U.S. dollars in 2018. Third Rock was unjustly rewarded from its deliberate induced infringement of the '179 and '061 Patents. In 2018, Nick Leschly was among the highest paid CEOs in the pharmaceutical industry, raking in approximately 24 million dollars. The foregoing financial gains would not have been possible without inducing Bluebird to infringe the '179 and '061 Patents.

163. As a founding member and partner at Third Rock, Neil Exter served in a key leadership role at Bluebird.

164. As a partner at Third Rock, Philip Reilly (i) was instrumental in creating Bluebird; (ii) served on the scientific advisory board of Bluebird; and (iii) served as the Chief Medical Officer at Bluebird from 2010 to 2011.

165. As founding member and partner at Third Rock, Nick Leschly (i) played an integral role in the overall formation, development and business strategy of Bluebird; (ii) served as the CEO at Bluebird for eleven years; and (iii) currently serves as a Board member of Bluebird.

166. On November 4, 2021, Bluebird announced that it had completed the tax-free spin-off of its oncology programs and portfolio into 2seventy bio, Inc. ("2seventy"). The majority of 2seventy's shares are owned by Bluebird and Third Rock. Nick Leschly is currently the President, CEO, and a member of the board of directors at 2seventy.

167. As founding member and partner at Third Rock, Daniel Lynch (i) served as a board member of Bluebird until November 4, 2021; and (ii) currently serves as a director at 2seventy.

168. As a direct result of Third Rock's inducing activities (past and current), Bluebird is engaging in infringing acts that are outside the scope of 35 U.S.C. § 271(e)(1). Third Rock is aware that Bluebird's activities are not solely for uses reasonably related to the development and submission of information to the FDA.

169. It was Third Rock's intent to cause and encourage Bluebird to engage in infringing acts that are outside the scope of 35 U.S.C. § 271(e)(1) that infringe the '179 and '061 Patents.

170. It was Third Rock's intent to cause and encourage Bluebird to engage in activities not solely for uses reasonably related to the development and submission of information to the FDA that infringe the '179 and '061 Patents.

171. As a direct result of Third Rock's inducing activities (past and current), Bluebird completed its submission of its BLA to the FDA for its Infringing Drug Product, which is manufactured using (and containing) the BB305 Vector. It was Third Rock's intent to cause and encourage Bluebird to complete the submission of its BLA with the FDA for the BB305 Vector, and Third Rock knows that the BB305 Vector infringes the '179 and '061 Patents.

172. As a direct result of Third Rock's inducing activities (past and current), Bluebird has engaged and continues to engage in non-regulatory conduct and post-FDA submission activities related to the commercialization of the BB305 Vector, which infringes the '179 and '061 Patents. Third Rock is aware that Bluebird's non-regulatory conduct and post-FDA submission activities, related to the commercialization of the BB305 Vector, directly infringes the '179 and '061 Patents.

173. It was Third Rock's intent to cause Bluebird to engage in non-regulatory conduct and post-FDA submission activities related to the commercialization of the BB305 Vector that infringe the '179 and '061 Patents.

174. Through its ownership interest, extensive control, and influence over Bluebird, Third Rock continues to actively induce infringement of the '179 and 061 Patents, by among other things, continuing to exert control over, and encourage and aid in Bluebird's infringement of the

'179 and '061 Patents, and Third Rock is aware that Bluebird's BB305 Vector directly infringes the '179 and '061 Patents.

175. Third Rock had and continues to have the specific intent to induce Bluebird's infringement, at least because Third Rock knows that its actions (both past and present) induced Bluebird's direct infringement of the '179 and '061 Patents.

176. Third Rock had actual knowledge of SRT's exclusive (worldwide) commercial license to the '179 and '061 Patents since no later than June 2009.

177. At a minimum, Third Rock was willfully blind that its actions (past and current) induce Bluebird to directly infringe and/or was willfully blind that the BB305 Vector directly infringes the '179 and '061 Patents, and acted, despite a risk of infringement, that was either known or so obvious to Third Rock that Third Rock should have known that its actions induced Bluebird's direct infringement of the '179 and '061 Patents.

178. Third Rock's willful and induced infringement of the Patents-in-Suit has damaged and will continue to damage SRT. SRT is entitled to recover damages sustained as a result of Third Rock's past and present wrongful inducement of directly infringing acts in an amount to be determined at trial.

179. SRT seeks past damages of no less than a reasonable royalty, which includes milestone payments based upon a hypothetical negotiation, and enhanced damages due to Defendants' willful misconduct.

FIRST CAUSE OF ACTION
Infringement of the '179 Patent

180. SRT repeats, realleges, and incorporates by reference the allegations in paragraphs 1 through 179 as if fully set forth herein.

181. SRT has an exclusive commercial license to the vectors that are within the scope of the claims of the '179 Patent.

182. Bluebird infringes a valid claim of the '179 Patent, either literally or under the doctrine of equivalents.

183. The '179 Patent covers recombinant lentiviral vectors having a region encoding a functional β-globin gene; and large portions of the β-globin locus control regions ("LCR"), which include DNase I hypersensitive sites HS2, HS3, and HS4, and provide expression of β-globin when introduced into a mammal, for example, a human, in vivo.

184. Claim 1 of the '179 Patent is directed to a recombinant vector comprising a nucleic acid encoding a functional globin operably linked to a 3.2-kb nucleotide fragment which consists essentially of three contiguous nucleotide fragments obtainable from a human β-globin LCR, the three fragments being a BstXI and SnaBI HS2-spanning nucleotide fragment of said LCR; a BamHI and HindIII HS3-spanning nucleotide fragment of said LCR; and a BamHI and BanII HS4-spanning nucleotide fragment of said LCR, said vector providing expression of the globin in a mammal in vivo.

185. Claim 23 of the '179 Patent is directed to a recombinant vector comprising a nucleic acid encoding a functional globin operably linked to a 3.2-kb nucleotide fragment which consists essentially of three nucleotide fragments obtainable from a human β-globin LCR, the three fragments being a BstXI and SnaBI, HS2-spanning nucleotide fragment of said LCR; a BamHI and HindIII, HS3-spanning nucleotide fragment of said LCR; and a BamHI and BanII, HS4-spanning nucleotide fragment of said LCR, wherein the HS3-spanning nucleotide fragment and the HS4-spanning nucleotide fragment are adjacent to each other and the vector further comprises

2 GATA-1 binding sites at the junction between the HS3-spanning and HS4-spanning nucleotide fragments, said vector providing expression of the globin in a mammal in vivo.

186. As demonstrated in the '179 Patent claim chart (*see* Exhibit L), Bluebird's BB305 Vector infringes at least claims 1 and 23 of the '179 Patent, either literally or under the doctrine of equivalents.

187. Bluebird has committed and continues to commit these acts of infringement of the '179 Patent without a license or authorization.

188. As a result of Bluebird's infringement of the '179 Patent, SRT has suffered damages and will continue to suffer damages, including damages awardable under 35 U.S.C. §§ 284 and 285.

189. Third Rock's induced infringement of the '179 Patent has been and continues to be willful. Third Rock had knowledge of its induced infringement of the '179 Patent, including at least for reasons that, in 2009 and before the formation of Bluebird, Third Rock was informed that the '179 Patent's globin vector technology was licensed to SRT. Third Rock continued to induce Bluebird's directly infringing activities despite having knowledge of Bluebird's direct infringement or being willfully blind to its inducement of Bluebird's direct infringement.

190. Bluebird's infringement of the '179 Patent has been willful and continues to be willful. Bluebird has had and currently has knowledge of its infringement of the '179 Patent, including at least for the reason that Bluebird had discussions with the Inventors and MSKCC involving the identification of potential areas of collaboration, including vector design and next-generation Sickle Cell Disease and Beta Thalassemia vectors. Bluebird continued to infringe despite having knowledge of its infringement or being willfully blind to its infringement.

191. Bluebird's infringing conduct has caused and is causing irreparable harm to SRT

for which SRT has no adequate remedy at law, and such irreparable harm will continue unless and until Bluebird is enjoined by this Court.

SECOND CAUSE OF ACTION
Infringement of the '061 Patent

192. SRT repeats, realleges, and incorporates by reference the allegations in paragraphs 1 through 191 as if fully set forth herein.

193. SRT has an exclusive (worldwide) commercial license to the vectors that are within the scope of the claims of the '061 Patent.

194. Bluebird infringes a valid claim of the '061 Patent, either literally or under the doctrine of equivalents.

195. The '061 Patent covers recombinant lentiviral vectors having a region encoding a functional β-globin gene; and large portions of the β-globin LCR, which include DNase I hypersensitive sites HS2, HS3 and HS4, and provide expression of β-globin when introduced into a mammal, for example a human, in vivo.

196. Claim 1 of the '061 Patent is directed to an isolated mammalian hematopoietic progenitor cell or an isolated mammalian stem cell comprising a recombinant lentiviral vector.

197. Claim 11 of the '061 Patent is directed to a method of making a mammalian hematopoietic progenitor cell or a mammalian stem cell.

198. As demonstrated in the '061 Patent claim chart (*see* Exhibit M) the BB305 Vector infringes at least claims 1-2, 5, 7-8, 11, and 15 of the '061 Patent, either literally or under the doctrine of equivalents.

199. Bluebird has committed and continues to commit these acts of infringement of the '061 Patent without license or authorization.

200. As a result of Bluebird's infringement of the '061 Patent, SRT has suffered damages and will continue to suffer damages, including damages awardable under 35 U.S.C. §§ 284 and 285.

201. Third Rock's induced infringement of the '061 Patent has been and continues to be willful. Third Rock had knowledge of its induced infringement of the '061 Patent, including, at least for reasons that, in 2009 and before the formation of Bluebird, Third Rock was informed that the '061 Patent's globin vector technology was licensed to SRT. Third Rock continued to induce Bluebird's directly infringing activities despite having knowledge of Bluebird's direct infringement or being willfully blind to its inducement of Bluebird's direct infringement.

202. Bluebird's infringement of the '061 Patent has been willful and continues to be willful. Bluebird has had and currently has knowledge of its infringement of the '061 Patent, including at least for the reason that Bluebird had discussions with the Inventors and MSKCC involving the identification of potential areas of collaboration, including vector design and next-generation Sickle Cell Disease and Beta Thalassemia vectors. Bluebird continued to infringe despite having knowledge of its infringement or being willfully blind to its infringement.

203. Bluebird's infringing conduct has caused and is causing irreparable harm to SRT for which SRT has no adequate remedy at law, and such irreparable harm will continue unless and until Bluebird is enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff SRT respectfully requests that the Court enter judgment in its favor and against Defendants Bluebird and Third Rock as follows:

A. Enter judgment that Bluebird has infringed, and continues to infringe a valid claim of the '179 and '061 Patents, either literally or under the doctrine of equivalents;

B. Enter judgment that Bluebird's making, having made, using, importing, selling or offering to sell, the BB305 Vector infringes, at least, claims 1 and 23 of the '179 Patent, either directly or under the doctrine of equivalents;

C. Enter judgment that Bluebird's making, having made, using, importing, selling or offering to sell the BB305 Vector infringes, at least, claims 1-2, 5, 7-8, 11, and 15 of the '061 Patent, either directly or under the doctrine of equivalents;

D. Enter judgment that Third Rock induced Bluebird's direct infringement of, at least, claims 1 and 23 of the '179 Patent.

E. Enter judgment that Third Rock induced Bluebird's direct infringement of, at least, claims 1-2, 5, 7-8, 11, and 15 of the '061 Patent.

F. Permanently enjoin Bluebird, its officers, employees, agents, representatives, attorneys, and others acting on its behalf from engaging in any activity that is not solely for uses reasonably related to its BLA for the BB305 Vector submitted to the FDA until after expiration of the '179 and '061 Patents;

G. Permanently enjoin Bluebird, its officers, employees, agents, representatives, attorneys, and others acting on its behalf from engaging in any commercialization activities related to the BB305 Vector, including barring Bluebird from making, having made, marketing, distributing, offering to sell, or selling the BB305 Vector until after expiration of the '179 and '061 Patents;

H. Order Bluebird, its officers, employees, agents, representatives, attorneys, and others acting on its behalf to cease any and all marketing and/or commercialization activities related to the BB305 Vector until after expiration of the '179 and '061 Patents;

I. Alternatively, award, in lieu of an injunction, ongoing royalties;

J. Award SRT damages adequate to compensate SRT for both Defendants' past and present infringement of the Patents-in-Suit, including supplemental damages for any post-verdict infringement up until entry of the final judgment with an accounting as needed, together with interest and costs under 35 U.S.C. § 284;

K. Enter judgment that Defendants' infringement is willful and that the damages awarded to SRT should be enhanced for up to three times the actual damages awarded;

L. Declare that this case is exceptional and an award to SRT of its costs, expenses, and reasonable attorneys' fees under 35 U.S.C. § 285 and all other applicable statutes and rules in common law that would be appropriate, with pre- and post-judgment interest thereon;

M. Award SRT pre-judgment and post-judgment interest; and

N. Award such other and further relief as the Court may deem just and proper under the circumstances.

DEMAND FOR JURY TRIAL

Pursuant to Fed. R. Civ. P. 38(b) and D. Del. LR 38.1, SRT hereby demands a trial by jury as to all issues so triable in this case.

Dated: March 7, 2022

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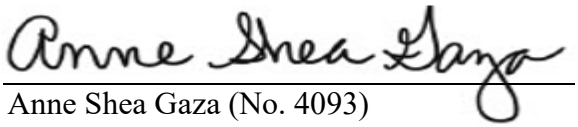

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